



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,716	01/30/2004	Warren L. Starkebaum	P-9902.02	5132
27581	7590	04/11/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			HELLER, TAMMIE K	
		ART UNIT		PAPER NUMBER
				3766
DATE MAILED: 04/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/768,716	STARKEBAUM, WARREN L.
	Examiner	Art Unit
	Tammie Heller	3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 January 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 14-40 is/are rejected.
- 7) Claim(s) 2-13 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 January 2004 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The abstract of the disclosure is objected to because the abstract is not of adequate length to provide a thorough overview of the technical disclosure of the patent present the main inventive features. Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claim 32 is objected to because of the following informalities: the claim refers to the system of claim 39, however claim 39 is directed to a computer-readable medium. It is believed applicant intended claim 32 to refer to claim 29 and the Examiner has considered it as such. Appropriate correction is required.

4. Claim 17 is objected to because of the following informalities: the claim appears to be an essential duplicate of claim 16. Appropriate correction is required.

5. Claim 23 is objected to because of the following informalities: the claim recites "a signal frequency of 1 approximately 4 Hz", however it is unclear whether Applicant intended a signal frequency of 1 or 4 Hz, or as in claims 36 and 40, a signal frequency

of 14 Hz. Based on claims 36 and 40, the Examiner has considered claim 23 to require a signal frequency of 14 Hz. Appropriate correction is required.

6. Claim 26 is objected to because of the following informalities: the claim recites "a memory means to data associated storing the external command", however it is believed applicant intended the claim to recite "a memory means to store data associated with the external command". Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 14, respectively, of copending Application No. 10/768,995. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 14, 23, 24, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 23, 25, 37, and 38, respectively, of copending Application No. 10/801,230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/441,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of copending Application No. 10/441,785. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 14 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of copending Application No. 10/441,786. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 14-21, 24-33, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al. (U.S. Patent No. 5,188,104), herein Wernicke. Regarding claims 14, 24, and 37, Wernicke discloses stimulus generator 10 which generates an electric stimulation signal (see col. 8, ln. 19-20 and Figure 1), stimulation electrodes 40, which apply the stimulation signal to a gastrointestinal tract of a patient (see Figure 2 and col. 9, ln. 15), and microprocessor 27 for controlling the generation of stimulation (see col. 9, ln. 10). Regarding the computer readable medium of claim 37, Wernicke discloses computer 50 which adjusts the stimulation parameters (see col. 9, ln. 21-26).

15. Regarding claims 15 and 29, Wernicke discloses a communication module to wireless receiver external commands from an external module (see col. 9, ln. 57-62).

16. Regarding claims 16, 17, 27, and 38, Wernicke discloses that the stimulation signal has a frequency between 5 and 150 Hz (see the Table in column 13). Based on Applicant's disclosure on page 15, paragraph 53, line 4 that a suitable exemplary frequency is in the range of approximately 0.5 Hz to 500 Hz, the Examiner takes the

position that the system of Wernicke has a stimulation signal with a frequency significantly greater than a normal gastric slow wave of the patient.

17. Regarding claims 18, 25, and 30, Wernicke discloses that the external command may be a command operation and the time of day at which the command operation is to occur (see Abstract, ln. 10-12).

18. Regarding claims 19 and 31, Wernicke discloses that the processor may initiate electric stimulation in response to an external command (see col. 3, ln. 58-59).

19. Regarding claims 20 and 32, Wernicke discloses that the processor may terminate electric stimulation in response to an external command (see col. 3, ln. 58-59).

20. Regarding claims 21 and 33, Wernicke discloses that the electric stimulation signal comprises a set of signal parameters comprising an amplitude, a signal frequency, a pulse width, and a duty cycle (see col. 13, ln. 54-58).

21. Regarding claim 26, Wernicke discloses that a memory may be implemented to store data associated with an external command (see col. 12, ln. 62-65).

22. Regarding claim 28, Wernicke discloses that satiety is induced through utilization of the disclosed apparatus (see col. 6, ln. 6-8 and 27).

23. Claims 14, 16, 17, 21-24, 27, 28, and 33-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen (U.S. 2004/0088022). Regarding claims 14, 24, and 37, Chen discloses a method for treating obesity which utilizes a stimulator to generate an electric stimulation signal, a stimulation electrode, and a processor (see Claim 1). It is

inherent within the method of Chen that a computer readable medium is incorporated in order to facilitate control of the stimulation parameters by the processor.

24. Regarding claims 16, 17, 27, and 38, Chen discloses that the stimulation signal has a frequency between 10 and 100 Hz (see paragraph 6, ln. 19). Based on Applicant's disclosure on page 15, paragraph 53, line 4 that a suitable exemplary frequency is in the range of approximately 0.5 Hz to 500 Hz, the Examiner takes the position that Chen discloses a stimulation signal frequency significantly greater than a normal gastric slow wave of the patient.

25. Regarding claims 21 and 33, Chen discloses that the electric stimulation signal comprises a set of signal parameters comprising an amplitude, a signal frequency, a pulse width, and a duty cycle (see paragraph 6, ln. 12-20).

26. Regarding claims 22, 34, 35, and 39, Chen discloses that the set of signal parameters comprises an amplitude between 0.5 and 15 mA, a signal frequency between 10 and 100 Hz, an on duty cycle between 0.1 and 0.5 seconds, and an off duty cycle between 4.5 and 5 seconds (see paragraph 6, ln. 12-20). Further, Chen discloses that in a particular embodiment, the pulse width is 334 microseconds (see paragraph 26, ln. 8).

27. Regarding claims 23, 36, and 40, Chen discloses that the signal amplitude is preferably 6 mA which is approximately 5 mA; the signal frequency is between 10 and 100 Hz, therefore it may be approximately 14 Hz; the pulse width is 334 microseconds, which is approximately 330 microseconds; the on duty cycle is between 0.1 and 0.5 seconds, which is approximately 0.1 seconds; and the off duty cycle is between 4.5 and

5 seconds, which is approximately 5 seconds (see paragraph 6, ln. 12-20 and paragraph 26, ln. 8-9).

28. Regarding claim 28, Chen discloses inducing satiety in a patient (see paragraph 7, ln. 14).

Allowable Subject Matter

29. Claims 1-13 would be allowable if the rejection(s) under obviousness-type double patenting, as set forth in this Office action, were overcome.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gordon et al. (U.S. Patent No. 6,684,104) which discloses apparatuses for stimulation the gastrointestinal tract;

Boveja (U.S. Patent No. 6,611,715) which discloses a system and method for stimulation of the gastrointestinal tract for treatment of obesity;

Marchal et al. (U.S. Patent No. 6,853,862) which discloses a gastroelectric stimulator to influence pancreatic secretions; and

Castel (U.S. Patent No. 4,535,777) which discloses a method of stimulating body tissue

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-

1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

TKH